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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/943,751	08/30/2001	Dan Stoianovici	56436(71699)	8459
21874	7590	03/23/2004		EXAMINER
EDWARDS & ANGELL, LLP				NGUYEN, VI X
P.O. BOX 55874				
BOSTON, MA 02205			ART UNIT	PAPER NUMBER
			3731	//

DATE MAILED: 03/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/943,751	STOIANOVICI ET AL.
Examiner	Art Unit	
Victor X Nguyen	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
 THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 17 December 2003.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-47 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) 16 and 17 is/are allowed.
 6) Claim(s) 1-15, 18-25, 29-36, 39, 42, 43 and 46-55 is/are rejected.
 7) Claim(s) 26-28, 37, 38, 40, 41, 44 and 45 is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. In response to applicant's amendment of 12/17/2003, the examiner has removed prior drawings objection.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-9, 13-15, 18-25, 29-34, 36, 39, 42 and 46-55 are rejected under 35 U.S.C. 102 (b) as being anticipated by Paltiel (U.S. 5,647,373).

Note in figures 1, 4 and 5-6 a needle guide enabling the physician to get to the target as close as possible having all the limitation of claims 1, 46-49, 52 and 55, including: the segment of item 42 can be characterized as a first arm (42) that arranges to support the penetrating member (5). A first drive mechanism (25) couples to the first arm (42); and wherein the penetrating member (5) proximal portion disposes in the target area, thereby translating the penetrating member proximal portion towards the target area. Note: The introductory statement of intended use and all other functional statements have been carefully considered but are deemed not to impose any structural limitations on the claims distinguishable over the Paltiel reference which is capable of being used as claimed if one desires to do so.

Regarding claims 2 and 3, wherein the first arm (42) rotates to support the penetrating member (5). A second drive mechanism (45) couples to the penetrating member to cause the

penetrating member to rotate about a long axis; and wherein the first (25) and second (45) drive mechanisms are configured so that rotating of the penetrating member is independently controlled.

Regarding claims 4 and 5-6, wherein the first (25) and second (45) drive mechanisms are configured so as to rotate of the penetrating member with different rotational speeds.

Regarding claims 7 and 8-9, wherein the second arm (43) couples to the first drive mechanism (25). The second arm (43) further includes a guide mechanism (fig. 2) which has the penetrating member (5); and wherein the guide mechanism is capable of guiding differently sized the penetrating member (6).

Regarding claims 13 and 14-15, wherein the first drive mechanism (25) includes a screw (23) coupled to the first arm (42); and wherein the first drive mechanism (25) includes a motor (45) coupled to the screw; wherein the first arm (42) translates in one of the direction responsive to the direction of rotation of the motor.

Regarding claims 18 and 39, wherein a controller (32) arranges to select and control the first and second drive mechanisms.

Regarding claims 19-20, wherein the controller (32) includes a plurality of pre-established penetrating member (5) from an initial position to the target area.

Regarding claims 21-22, wherein the controller (32) rotates of the penetrating member (5) and also to arrange to rotate the penetrating member with different rotational speeds.

Regarding claims 23 and 24-25, wherein the controller (32) translates the penetrating member in a back and forth manner; the device further includes a sensor (labeled in col. 2, lines

64-67 and col. 3, lines 1-5); and wherein the penetrating member is capable of performing any one of injecting therapeutic agents into the target area (col. 3, lines 8-41).

Regarding claims 29,50-51 and 53-54, wherein a first arm (42) arranges to support the penetrating member (5). A first drive mechanism (25) couples to the first arm (42), thereby translating the penetrating member proximal portion in a direction towards the target area; and wherein the penetrating member proximal portion disposes in the target area. A second arm (43) couples to the first drive mechanism (25). A second drive mechanism (45) couples to the penetrating member (6) to cause the penetrating member to rotate about a long axis. Note: The introductory statement of intended use and all other functional statements have been carefully considered but are deemed not to impose any structural limitations on the claims distinguishable over the Paltiel reference which is capable of being used as claimed if one desires to do so.

Regarding claims 30-31, wherein the first (25) and second (45) drive mechanisms are configured so as to rotate of the penetrating member with independently controlled.

Regarding claims 32 and 33-34, the first (25) and second (45) drive mechanisms are configured so as to rotate of the penetrating member with different rotational speeds; and wherein the second arm (43) includes a guide mechanism (fig. 5) which includes the penetrating member (5).

Regarding claim 36, wherein a screw (23) couples to the first arm (42); a motor (45) couples to the screw (23); and wherein the first arm (42) translates in one the direction responsive to the direction of rotation of the motor.

Claims 1-6 and 46-47 are rejected under 35 U.S.C. 102 (b) as being anticipated by Stoianovici et al (WO 98/36688).

Stoianovici et al show in figures 1-3, a device having all the limitation of claims 1 and 46-47, including: a first arm (39) arranges to support the penetrating member (7). A first drive mechanism (37) couples to the first arm (39); and wherein the penetrating member (7) proximal portion disposes in the target area, thereby translating the penetrating member proximal portion towards the target area. Note: The introductory statement of intended use and all other functional statements have been carefully considered but are deemed not to impose any structural limitations on the claims distinguishable over the Stoianovici et al reference which is capable of being used as claimed if one desires to do so.

Regarding claims 2 and 3, wherein the first arm (39) rotates to support the penetrating member (7). A second drive mechanism (fig. 1) couples to the penetrating member to cause the penetrating member to rotate about a long axis; and wherein the first and second drive mechanisms are configured so that rotating of the penetrating member is independently controlled.

Regarding claims 4 and 5-6, wherein the first and second drive mechanisms are configured so as to rotate of the penetrating member (7) with different rotational speeds.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10-12, 35 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paltieli (U.S. 5,647,373).

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Regarding claims 10-12, 35 and 43, Paltiel fails to disclose the first arm and the second arm includes a detachable portion and a latching mechanism. It would have been obvious to one having ordinary skill in the art at the same time the invention was made to construct the Paltiel's device with the first arm and the second arm includes a detachable portion and a latching mechanism, since it has been held to be within the general skill of worker in the art to allow the operator to replace the needle conveniently and to prevent the needle being contaminated as a matter of obvious engineering choice. In re Larson, 144 USPQ 347 (CCPA 1965); In re Lockart, 90 USPQ 214 (CCPA 1951).

Allowable Subject Matter

4. Claims 16-17 are allowed.

Claims 26-28, 37-38, 40-41 and 44-45 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The following is a statement of reasons for the indication of allowable subject matter: The prior art fails to disclose wherein the first drive mechanism includes a linear guide which restrain motion of the first arm and a sliding member which is secured to the first arm.

Response to Amendment

5. Applicant's arguments with respect to claims 1,29,42 and 46 have been considered but are moot in view of the new ground(s) of rejection. Applicant is asked to please refer to the modified prior art rejection above wherein examiner addresses applicant's concerns regarding prior art rejections. For example, Note in figures 1, 4 and 5-6 a needle guide enabling the physician to get to the target as close as possible including: the segment of item 42 can be

characterized as a first arm (42), while item 43 is a second arm that arranges to support the penetrating member (5). A first drive mechanism (25) couples to the first arm (42); and wherein the penetrating member (5) proximal portion disposes in the target area, thereby translating the penetrating member proximal portion towards the target area. Note: The introductory statement of intended use and all other functional statements have been carefully considered but are deemed not to impose any structural limitations on the claims distinguishable over the Paltiel reference which is capable of being used as claimed if one desires to do so.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Victor X Nguyen whose telephone number is (703) 305-4898. The examiner can normally be reached on M-F (8-4.30 P.M.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on (703) 308-2496. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Victor X Nguyen
Examiner
Art Unit 3731

Vn VJ
March 19, 2004



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